DEPARTMENT OF HEALTH & HUMAN SERVICES M1009N Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

June 20, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-50

Kevin J. Johnsrud
President
Versa Electronics
5205 Highway 169
Plymouth, Minnesota 55442

Dear Mr. Johnsrud:

We are writing to you because on May 2-9, 1997, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving portable audiometers which are made by your firm.

Under United States Federal law [the Federal Food, Drug and Cosmetic Act (the Act)], these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. Audiometers are medical devices as defined by Section 201(h) of the Act.

The law requires that manufacturers of medical devices adhere to Current Good Manufacturing Practice (CGMP) regulations for Medical Devices as specified in Title 21, Code of Federal Regulations (CFR), Part 820, in the methods used in, facilities or controls used for manufacturing, packing, storage or installation of medical devices.

contracts. Additionally, no pending applications for pre-market approval (PMAs) or export approval requests will be approved and no pre-market notifications [Section 510(k)s] will be found to be substantially equivalent for products manufactured for your facility until the violations have been corrected.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you received this letter of the steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Compliance Officer Howard Manresa at the address indicated on the letterhead.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of Current Good Manufacturing Practices for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about how FDA marketing requirements affect your particular device or about the content of this letter, please feel free to contact Mr. Manresa at (612) 334-4100 ext. 156.

Sincerely,

James I. Roberts
Acting Director
Minneapolis District

HEM/ccl

Enclosure: FDA-483, 5/9/97